

Comparison of prostaglandin E₂ tablets or Foley catheter for labour induction in grand multiparas

M.I. Al-Taani¹

مقارنة بين البروستاغلاندين E₂ وبين قنطرة فولبي في تحريض المخاض لدى من زاد لديهن عدد الولادات عن خمسة
محمد الطعاني

الخلاصة: قارن الباحث بين كفاءة وسلامة وحصائل استخدام البروستاغلاندين E₂، واستخدام قنطرة فولبي في تحريض المخاض لدى من ولدت أكثر من خمس مرات. ففي إحدى المستشفيات الأردنية درست 147 امرأة ممن كانت لديهن أحراز بيشوب تساوي أو تقل عن 5 بإعطاء 3 ميلي غرام من البروستاغلاندين E₂ على شكل أقراص مهبلية عند 75 منهن، أو باستخدام قنطرة فولبي بضغط 50 ميلي لتر فيها لدى 72 امرأة أخرى. وقد لوحظ أن التغيير في أحراز بيشوب أعلى بكثير لدى من استخدم لديهن البروستاغلاندين E₂ بالمقارنة مع من استخدم لديهن قنطار فولبي، كما كان الزمن المنقضي بين بدء التحريض وبين الولادة أقصر بكثير عند من استخدم لديهن البروستاغلاندين E₂. كذلك كان عدد اللواتي احتجن للأوكسيتوسين لتقوية المخاض أكبر في من استخدمت لديهن قنطرة فولبي ممن استخدم لديهن البروستاغلاندين E₂. وكانت الضائقة الجنينية أكثر تكراراً من الناحية الإحصائية. وهكذا تدلّ الدراسة على أن من الأفضل استخدام أقراص مهبلية من البروستاغلاندين E₂ لإنضاج عنق الرحم ولتحريض المخاض.

ABSTRACT The efficacy, safety and outcome of prostaglandin (PG)E₂ was compared with Foley catheter for labour induction in grand multiparous women. At a hospital in Jordan, 147 women with Bishop score ≤ 5 were randomized to receive 3 mg PGE₂ vaginal tablets (n = 75) or 50 mL intracervical Foley catheter (n = 72). The change in Bishop score was significantly higher in the PGE₂ group than the catheter group, and time from induction to delivery was significantly shorter in the PGE₂ group. Significantly more women needed oxytocin for labour augmentation in the catheter than the PGE₂ group and fetal distress was significantly more frequent. For grand multiparas, PGE₂ vaginal tablets may be preferable for ripening the cervix as well as for labour induction.

Comparaison des ovules de prostaglandine E₂ et de la sonde de Foley pour le déclenchement du travail chez des grandes multipares

RÉSUMÉ L'efficacité, l'innocuité et l'effet de la prostaglandine (PG) E₂ ont été comparés avec la sonde de Foley pour le déclenchement du travail chez des grandes multipares. Dans un hôpital en Jordanie, 147 femmes dont le score de Bishop était inférieur ou égal à 5 ont été randomisées pour recevoir des ovules vaginaux de PGE₂ de 3 mg (n = 75) ou une sonde de Foley intracervicale de 50 mL (n = 72). La modification du score de Bishop était significativement plus importante dans le groupe de la PGE₂ que dans le groupe de la sonde, et le temps entre le début du travail et l'accouchement était significativement plus court dans le groupe de la PGE₂. Un nombre significativement plus important de femmes a eu besoin d'ocytocine pour augmenter le travail dans le groupe de la sonde que dans le groupe de la PGE₂ et la souffrance foetale était significativement plus fréquente. Chez les grandes multipares, les ovules vaginaux de PGE₂ peuvent être préférables pour la maturation cervicale ainsi que pour l'induction du travail.

¹Department of Obstetrics and Gynaecology, Queen Alia Military Hospital, Royal Medical Services, Amman, Jordan.

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Introduction

The process of cervical ripening usually commences before labour begins; the cervix undergoes significant biochemical changes over a period lasting from 12 hours to 6–8 weeks [1]. It is believed to be controlled by certain hormones (in particular prostaglandin E_2) that play a role in triggering uterine contractile activity [2]. So the state of the cervix has been suggested to be the most important factor in predicting the success rate of labour induction [3–5].

Calder et al. reported an increasing maternal and neonatal morbidity when labour induction begins with a Bishop score ≤ 3 [6]. Trofatter in 1992 reported a decrease in induction failure when using a variety of methods to ripen the cervix [7]. The use of prostaglandins for cervical ripening administered by any route has been reported to improve the rate of vaginal delivery and decrease the rate of caesarean section and instrument deliveries [8]. In addition, the use of a cervical catheter has been shown effective for cervical priming and leads to a favourable outcome [9].

Grand multiparity is considered a risk factor for maternal and neonatal morbidity. However, the subject is still under debate, with several authors reporting conflicting results as to whether a pregnancy is high risk or not because of its associated medical and obstetric complications [10–13]. Labour induction using prostaglandins in this high parity group has been viewed as a stressful and potentially dangerous procedure. Other reports on the use of prostaglandins in grand multiparas contradict this notion and have yielded a safe and effective method of labour induction [14–16].

Grand multiparity is common in Jordan. The total number of deliveries conducted in Queen Alia Military Hospital during the

study period (12 months) was 3684 and 1547 (42%) of these were to grand multiparous women. The number of inductions of labour conducted was 590 (16%). It is therefore important to study the efficacy, safety and outcome of vaginal prostaglandin (PG) E_2 tablet compared with intracervical Foley catheter insertion for induction of labour in this high parity group.

Methods

This prospective randomized study was carried out at Queen Alia Military Hospital, Amman, Jordan. Between September 2001 and August 2002, 147 grand multiparous women who had a clinically unfavourable cervix and indications for labour induction were recruited for the study. Patients were eligible for inclusion if they had a singleton pregnancy at term, vertex presentation, intact membranes, reassuring fetal heart tracings and Bishop score ≤ 5 . Women with previous caesarean section, ruptured membranes, contraindications for vaginal birth, suspected cephalopelvic disproportion or unexplained antepartum haemorrhage were excluded.

After written informed consent was obtained, patients were randomized to one of the 2 methods, using a random number table. For the first method, 75 women were given PGE $_2$ 3 mg vaginal tablet, inserted in the posterior vaginal fornix. This was repeated at 6-hour intervals, if needed. For the second method, 72 women were given a size 18 Foley catheter, inserted intracervically in order to pass the internal os using a sterile speculum technique. This was inflated with 50 mL distilled water and taped to the inner side of the thigh to produce a small traction.

For all women, vital signs were recorded on admission and blood was drawn for

complete blood count and cross-matching. General and systemic examinations followed by pelvic examination were performed. A fetal heart rate tracing was obtained upon admission and after the initiation of the induction method for a minimum time of 45 minutes. Abdominal and cervical examinations were performed at 4–6 hour intervals to diagnose the start of labour and to measure Bishop score changes, unless these were indicated at earlier times. Amniotomy was performed within 1–2 hours of the diagnosis of labour or as soon as clinically feasible.

The progress of labour was monitored every 2 hours. Labour abnormalities were defined by Friedman's criteria [16]. For these cases, oxytocin infusion was started for augmentation of labour, administered in the manner outlined by O'Driscoll and Meagher [17]. Intrapartum continuous fetal heart rate monitoring was performed.

The primary outcome measures were the route of delivery and the time required from beginning of the induction method to delivery. The secondary outcome measures were the change in Bishop score, intrapartum complications or the need for oxytocin for labour augmentation.

Comparison of continuous variables was made with Student *t*-test. Categorical variables were compared using the chi-squared or Fisher exact test. $P < 0.05$ was considered to indicate a significant difference.

Results

There were no significant differences in presenting characteristics between the 2 study groups (Table 1) and both groups had similar indications for labour induction (Table 2). Postdates and pre-eclampsia were the most frequent indications in both

Table 1 Presenting characteristics of grand multiparas treated with Foley catheter or prostaglandin E₂ (PGE₂) vaginal tablet for induction of labour

Characteristic	Catheter group (n = 72)	PGE ₂ group (n = 75)	P-value
Maternal age (years)	27.7 (5.5)	27.1 (5.7)	0.438
Gestational age (weeks)	39.4 (1.9)	39.5 (1.7)	0.721
Parity (No.)	7.7 (2.1)	7.4 (1.9)	0.176
Initial Bishop score	2.56 (1.40)	2.61 (1.30)	0.873

Values are shown as mean (standard deviation).
n = number of patients.

groups. The frequency of postdate pregnancies was significantly higher in the catheter group than the PGE₂ group ($P = 0.029$).

As shown in Table 3, the change in Bishop score was statistically significantly higher in the PGE₂ group than the Foley catheter group (mean $3.95 \pm$ SD 2.20 versus 3.10 ± 1.10) ($P < 0.01$). Significantly more women in the catheter group (49%) needed oxytocin for labour augmentation than in the PGE₂ group (20%) ($P < 0.001$).

The time from initiation of the induction method to delivery was significantly shorter in the PGE₂ group compared with the catheter group (16.5 ± 2.2 versus 20.5 ± 3.9 hours) ($P < 0.01$). Of women that were randomized to use PGE₂, 61% delivered within 16 hours after initiation of induction compared with 42% of those randomized to use the Foley catheter. This was a statistically significant difference ($P < 0.01$). There were 21 women who delivered after 24 hours in the catheter group, compared with 5 women in the PGE₂ group. This difference was highly statistically significant ($P < 0.001$).

Table 2 Indications for induction of labour in grand multiparas treated with Foley catheter or prostaglandin E₂ (PGE₂) vaginal tablet for induction of labour

Indication	Catheter group (n = 72)		PGE ₂ group (n = 75)		P-value
	No.	%	No.	%	
Postdates	29	40	23	31	0.029
Pre-eclampsia	20	28	24	32	0.164
Diabetes	8	11	12	16	0.118
Suspected IUGR	10	14	11	15	0.693
Suspected macrosomia	5	7	5	7	0.999

IUGR = intrauterine growth restriction.
n = number of patients.

Table 3 Labour and delivery outcomes of grand multiparas treated with Foley catheter or prostaglandin E₂ (PGE₂) vaginal tablet for induction of labour

Outcome	Catheter group (n = 72)		PGE ₂ group (n = 75)		P-value
	No.	%	No.	%	
<i>Change in Bishop score</i>					
Mean (SD)	3.10	(1.10)	3.95	(2.20)	< 0.01
<i>Oxytocin required</i>	35	49	15	20	< 0.001
<i>Time from induction to delivery</i>					
< 16 hours	30	42	46	61	< 0.01
16–24 hours	21	29	24	32	0.228
> 24 hours	21	29	5	7	< 0.001
Mean (SD)	20.5	(3.9)	16.5	(2.2)	< 0.01
<i>Intrapartum complications</i>					
Fetal distress	11	15	6	8	0.01
Pyrexia	0	0	1	1	0.105
Failure to progress	6	8	7	9	0.617
Haemorrhage	3	4	5	7	0.91
<i>Delivery type</i>					
Spontaneous vaginal	52	72	57	76	0.166
Forceps	3	4	2	3	0.581
Vacuum	5	7	6	8	0.611
Caesarean section	12	17	10	13	0.147

SD = standard deviation.
n = number of patients.

There were no significant differences between the groups in intrapartum complications or in type of delivery but the frequency of fetal distress was significantly higher in the catheter group than the PGE₂ group ($P = 0.01$) (Table 3). In addition, there were no statistically significant differences in fetal outcomes (Apgar scores at 5 minutes, birth weight, admissions to the neonatal intensive care unit or meconium aspiration) between the 2 groups (Table 4). No more than 2 × 3 mg PGE₂ vaginal tablets were needed to achieve a clinically feasible cervix for amniotomy. No woman needed a blood transfusion. All women and their babies were discharged home in good condition.

Discussion

This study demonstrates that cervical ripening as well as labour induction in grand multiparas is safe using either PGE₂ or Foley catheter. Both methods were effective, but use of PGE₂ 3 mg vaginal tablets appeared to be superior to the intracervical insertion of a Foley catheter, in view of the higher change in Bishop score, shorter in-

terval from initiation to delivery and less need of oxytocin for labour augmentation. The current study agrees with other reports regarding the use and safety of PGE₂ vaginal tablets for labour induction in grand multiparas [14,18,19].

These findings contradict Sciscione et al. [9] who used PGE₂ intracervical gel compared with intracervical insertion of Foley catheter; however this gel is not readily available in our hospital. It is well known that some factors might affect the safety, absorption and efficacy of PGE₂, such as the vehicle, oily lubrication, humidity and possibly vaginal pH [20,21]. The difference in results may be attributed to the type of PGE₂ used, as the main effect of PGE₂ gel is cervical ripening and its contractile effect is considered to be small [22,23].

The most hazardous major complication of labour induction in grand multiparas is rupture of the uterus. Suggested risk factors for uterine rupture include multiparity, oxytocin use and the state of the cervix. The present study revealed no major complications. Comparison of intrapartum complications between groups showed no

Table 4 Fetal outcomes of grand multiparas treated with Foley catheter or prostaglandin E₂ (PGE₂) vaginal tablet for induction of labour

Outcome	Catheter group (n = 72)		PGE ₂ group (n = 75)		P-value
	No.	%	No.	%	
Mean (SD) birth weight (g)	3503	(575)	3452	(530)	0.319
Apgar score < 6 at 5 min	5	6.9	3	4.0	0.094
Admission to NICU	6	8.3	5	6.7	0.259
Meconium present	13	18.1	15	20.0	0.293

NICU = neonatal intensive care unit.

SD = standard deviation.

n = number of patients.

significant differences except for fetal distress which was significantly higher in the catheter group. Oxytocin was needed for labour augmentation in 48.6% and 20.0% of the Foley and PGE₂ groups, respectively. Outcome of labour and delivery compared favourably well in both groups. This demonstrates an equivalent safety of both methods, a finding that has been confirmed by others [14,24].

Furthermore, labour induction in grand multiparas with previous caesarean section has been reported to be safe, so too is the use of oxytocin when there is no contraindication for repeating the caesarean section [25,26]. However, in the current study

there were no cases of previous caesarean section. This might eliminate grand multiparity as a risk factor in the genesis of rupture of the uterus and in the increasing incidence of intrapartum complications as other studies indicate [12,13,27].

In the view of these findings, it can be concluded that cervical priming as well as labour induction in grand multiparous women is safe and effective when using either PGE₂ tablets or Foley catheter, together with the use of oxytocin if needed for labour augmentation, but in the absence of any contraindications to induction. The use of PGE₂ 3 mg vaginal tablets is preferred to the intracervical Foley catheter.

References

- Steiner AL, Creasy RK. Methods of cervical ripening. *Clinical obstetrics and gynecology*, 1983, 26:37–46.
- Garfield RE. Cellular and molecular bases for dystocia. *Clinical obstetrics and gynecology*, 1987, 30:3–18.
- Garrett WJ. Prognostic signs of surgical induction of labour. *Medical journal of Australia*, 1960, 49:29.
- Bishop EH. Pelvic scoring for elective induction. *Obstetrics and gynecology*, 1964, 24:266–8.
- Anderson AM, Turnbull AC. Relationship between the length of gestation and cervical dilatation, uterine contractility and other factors during pregnancy. *American journal of obstetrics and gynecology*, 1969, 105:1207–14.
- Calder AA, Embrey MP, Tait T. Ripening of the cervix with extra-amniotic prostaglandin E₂ in viscous gel before induction of labour. *British journal of obstetrics and gynaecology*, 1977, 84:264–8.
- Trofatter KF. Cervical ripening. *Clinical obstetrics and gynecology*, 1992, 35: 476–85.
- Keirse MJ N. Prostaglandins in preinduction cervical ripening. Meta-analysis of worldwide clinical experience. *Journal of reproductive medicine*, 1993, 38 (1 suppl.):89–100.
- Sciscione AC et al. A prospective randomized comparison of Foley catheter insertion versus intracervical prostaglandin E₂ gel for preinduction cervical ripening. *American journal of obstetrics and gynecology*, 1999, 180(1 Pt 1):55–60.
- Mwambingu FT, Al-Meshari AA, Akiel A. The problem of grandmultiparity in current obstetric practice. *International journal of gynaecology and obstetrics*, 1988, 26(3):355–9.
- Evaldson GR. The grandmultipara in modern obstetrics. *Gynecologic and obstetric investigation*, 1990, 30(4):217–23.
- Babinszki A et al. Perinatal outcome in grand and great-grand multiparity: effects of parity on obstetric risk factors. *American journal of obstetrics and gynecology*, 1999, 181(3):669–74.

13. Goldman GA et al. The grandmultipara. *European journal of obstetrics, gynecology, and reproductive biology*, 1995, 61(2):105–9.
14. Abou el-Leil LA, Nasrat AA, Fayed HM. Prostaglandin E2 vaginal pessaries in the grandmultipara with an unripe cervix, a comparison of different parity groups. *International journal of gynaecology and obstetrics*, 1993, 40(2):119–22.
15. Yamani TY, Rouzi AA. Induction of labor with vaginal prostaglandin-E2 in grand multiparous women. *International journal of gynaecology and obstetrics*, 1998, 62(3):255–9.
16. Friedman EA. The labour curve. *Clinics in perinatology*, 1981, 8(1):15–25.
17. O'Driscoll K, Meagher D. *Active management of labour. The Dublin experience*, 2nd ed. London, Baillière Tindall, 1986.
18. Sobande AA, Al-Bar HM, Archibong EI. A comparison of spontaneous labor with induced vaginal tablets prostaglandin E2 in grand multiparae. *Saudi medical journal*, 2001, 22(8):698–701.
19. Yamani TY, Rouzi AA. Induction of labor with vaginal prostaglandin-E2 in grand multiparous women with one previous cesarean section. *International journal of gynaecology and obstetrics*, 1999, 65(3):251–3.
20. Lyrenas S, Clason I, Ulmsten U. *In vivo* controlled release of PGE2 from a vaginal insert (0.8 mm, 10 mg) during induction of labour. *British journal of obstetrics and gynaecology*, 2001, 108(2):169–78.
21. Ramsey PS et al. Effect of vaginal pH on efficacy of the dinoprostone gel for cervical ripening/labor induction. *American journal of obstetrics and gynecology*, 2002, 186(4):843–6.
22. Seeras RC. Induction of labor utilizing vaginal vs. intracervical prostaglandin E2. *International journal of gynaecology and obstetrics*, 1995, 48(2):163–7.
23. Nuutila M, Kajanoja P. Local administration of prostaglandin E2 for cervical ripening and labor induction: the appropriate route and dose. *Acta obstetrica et gynecologica scandinavica*, 1996, 75(2):135–8.
24. St Onge RD, Connors GT. Preinduction cervical ripening: a comparison of intracervical prostaglandin E2 gel versus the Foley catheter. *American journal of obstetrics and gynecology*, 1995, 172(2 Pt 1):687–90.
25. Abu-Heija AT, Ali AM. Induction of labor in grand multiparous women and previous cesarean section: is it safe? *Gynecologic and obstetric investigation*, 2002, 53(2):121–4.
26. Ben-Aroya Z et al. Oxytocin use in grand-multiparous patients: safety and complications. *Journal of maternal–fetal medicine*, 2001, 10(5):328–31.
27. Toohey JS et al. The “dangerous multipara”: fact or fiction? *American journal of obstetrics and gynecology*, 1995, 172(2 Pt 1):683–6.